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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,795

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Michihiro Hide

2006-0009A

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7590

03/09/2009

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,795	Applicant(s) HIDE ET AL.	
	Examiner NORA M. ROONEY	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 12/08/2008 is acknowledged.
2. Claims 9 and 11-24 are pending.
3. Claims 11-24 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/03/2008.
4. Claim 9 is currently under examination as they read on a composition activating mast cell and basophils and having atopic dermatitis activity which is obtained from sweat.
5. In view of the amendment filed on 12/08/2008, only the following rejections are maintained.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
7. Claims 9 stands rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for the same reasons as set forth in the Office Action mailed on 09/05/2008.

Applicant's argument filed on 12/08/2008 has been fully considered, but is not found persuasive.

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Applicant argues:

"Applicants note that the first full paragraph on page 16 of the specification indicates that it can be determined whether a patient has atopic dermatitis or is at high risk for developing atopic dermatitis by assaying whether the patient has an antibody in their serum that binds to the composition of claim 1. This is a substantial, specific and credible utility.

The Office further appears to indicate that because the claimed fraction has not been completely characterized then further research would be required to determine the usefulness of the fraction. However, Applicants note that the above-noted utility does not require any further characterization and therefore the claimed composition meets the utility requirement. Applicants also note that the claimed composition is a product-by-process claim which is permitted under US practice.

Applicants note that the composition of claim 1 has utility and therefore the 35 U.S.C. § 101 rejection should be withdrawn. Applicants further note that since a credible utility has been shown, the above-noted enablement rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

It remains the Examiner's position that as disclosed, the composition of claim 1 does not have specific and substantial credible utility. Applicant has not determined the identity of the sweat fraction that can be used for antibody binding to determine atopic dermatitis. The specification disclosed a description of a method of purifying a human sweat fraction that has the functional characteristics of being able to activate mast cells and basophils upon binding to self-IgE and being able to induce atopic dermatitis, but neither the identity, biological role of the sweat fraction nor its significance has been disclosed. After further research, specific and substantial credible utility might be found. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. As such, further research would be required. Since the instant specification does not disclose a credible "real world" use for the sweat fractions, then the claimed invention as disclosed does not meet the requirements of 35 U.S. C. § 101 as being useful.

Applicant's argument that determining whether a patient has atopic dermatitis or is at a high risk for developing atopic dermatitis by assaying whether the patient has an antibody in their serum that binds the composition of claim 1 does not require further characterization of the composition of claim 1 is unpersuasive because the process of obtaining the composition requires further research and characterization. Applicants have essentially asserted that sweat contains a mast cell activating fraction that binds an antibody associated with disease, wherein the disease is associated with antibodies that bind mast cell activating compounds. Therefore, the asserted utility is neither specific nor substantially credible and requires significant further characterization.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 9 stands rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements for the same reasons as set forth in the Office Action mailed on 09/05/2008.

Applicant's argument filed on 12/08/2008 has been fully considered, but is not found persuasive.

Applicant argues:

"The Office's position is that the structure of the recited compound is an essential step. Applicants respectfully disagree. Applicants note that claim 9 is a product-by-process claim as permitted under US

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practice. Applicants note that such claim can be seen as an extract, which are commonly granted patents. Thus, this rejection is untenable and should be withdrawn. "

It remains the Examiner's position that it is unclear what the recited composition comprises because the recited composition is being claimed by functional language instead of structure. Applicant's assertion that the composition is a product by process is not persuasive to overcome the instant rejection as the process recited is not specific enough to result in any particular composition. In particular, there are no specific method steps recited, therefore, the resulting composition is also not specific and indefinite.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 9 stands rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation for the same reasons as set forth in the Office Action mailed on 09/05/2008.

Applicant's argument filed on 12/08/2008 has been fully considered, but is not found persuasive.

Applicant argues:

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"Applicants note that the first full paragraph on page 16 of the specification indicates that it can be determined whether a patient has atopic dermatitis or is at high risk for developing atopic dermatitis by assaying whether the patient has an antibody in their serum that binds to the composition of claim 1. This is a substantial, specific and credible utility.

The Office further appears to indicate that because the claimed fraction has not been completely characterized then further research would be required to determine the usefulness of the fraction. However, Applicants note that the above-noted utility does not require any further characterization and therefore the claimed composition meets the utility requirement. Applicants also note that the claimed composition is a product-by-process claim which is permitted under US practice.

Applicants note that the composition of claim 1 has utility and therefore the 35 U.S.C. § 101 rejection should be withdrawn. Applicants further note that since a credible utility has been shown, the above-noted enablement rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

It remains the Examiner's position that as disclosed, the composition of claim 1 does not have specific and substantial credible utility. Applicant has not determined the identity of the sweat fraction that can be used for antibody binding to determine atopic dermatitis. Further, the instant claims require the interaction of two uncharacterized elements. The first element is human own antibodies that can bind a sweat fraction and induce atopic dermatitis and the second is a sweat fraction that can bind human own antibodies and induce atopic dermatitis. No structural characteristics are given for either element. The specification disclosed a description of a method of purifying a human sweat fraction that has the functional characteristics of being able to activate mast cells and basophils upon binding to self-IgE of atopic dermatitis patients and being able to induce atopic dermatitis, but neither the identity, biological role of the sweat fraction nor its significance has been disclosed. After further research, specific and substantial credible utility might be found. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. As such, further research would be required. Since the instant specification does not disclose a

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credible “real world” use for the sweat fraction, then the claimed invention as disclosed does not meet the requirements of 35 U.S. C. § 101 as being useful.

Applicant's argument that determining whether a patient has atopic dermatitis or is at a high risk for developing atopic dermatitis by assaying whether the patient has an antibody in their serum that binds the composition of claim 1 does not require further characterization of the composition of claim 1 is unpersuasive because the process of obtaining the composition requires further research and characterization. Applicants have essentially asserted that sweat contains a mast cell activating fraction that binds unspecified antibodies of atopic dermatitis patients that are associated with disease, wherein the disease is associated with unspecified antibodies that bind mast cell activating compounds. Therefore, the asserted utility is neither specific nor substantially credible and requires significant further characterization.

12. Claims 9 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a method for purifying human sweat; does not reasonably provide enablement for a composition comprising a fraction activating mast cells and basophils upon binding to a human own IgE antibody and having an atopic dermatitis inducing activity, **which is obtained from sweat** through the following steps comprising: filtering human sweat, removing insoluble matters and collecting the filtrate; mixing the filtrate with a ConA-affinity carrier and collecting the supernatant; and separating a fraction having a histamine-releasing activity from the supernatant by anion exchange column chromatography and reverse phase column

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chromatography wherein the fraction activates mast cells and basophils upon binding to a human own IgE antibody and has atopic dermatitis inducing activity of claim 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons as set forth in the Office Action mailed on 09/05/2008.

Applicant's argument filed on 12/08/2008 has been fully considered, but is not found persuasive.

Applicant argues:

"Applicants respectfully traverse this rejection as applied to amended claim 9. Applicants note that in order to clarify the claimed invention and without acquiescence to the correctness of the Office's positions, claim 9 has been amended to indicate that the fraction activates mast cells and basophils upon binding to a human own IgE antibody and has atopic dermatitis inducing activity. Thus, as taught in the specification, such sweat can be obtained from a patient with atopic dermatitis. Thus, it is respectfully submitted that the claimed composition can be obtained without undue experimentation and therefore this rejection, as applied to the amended claim, is untenable and should be withdrawn. "

It remains the Examiner's position that Applicants have not isolated or characterized the fraction of sweat that is responsible for the claimed functional activities. As such, without structure, Applicants are not enabled for the composition. Further, contrary to Applicant's assertion, one of ordinary skill in the art would be required to perform undue experimentation to obtain the composition recited because it is excessive and undue to analyze every fraction of the human sweat supernatant for the claimed function. Further, the claims as recited read on human sweat fractions that exhibit histamine releasing activity of any cells from any patient. Applicants have not demonstrated a correlation between histamine releasing activity in any cell with the

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ability to induce atopic dermatitis. Applicant's argument that structure is unnecessary because the claims are directed to a product by process is unpersuasive. The function alone is not sufficient to identify the instant compound, irrespective of the method of production. Therefore, the rejection stands.

13. Claims 9 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: a method for purifying human sweat.

Applicant is not in possession of: **a composition** comprising a fraction activating mast cells and basophils upon binding to a human own IgE antibody and having an atopic dermatitis inducing activity, **which is obtained from sweat** through the following steps comprising: filtering human sweat, removing insoluble matters and collecting the filtrate; mixing the filtrate with a ConA-affinity carrier and collecting the supernatant; and separating a fraction having a histamine-releasing activity from the supernatant by anion exchange column chromatography and reverse phase column chromatography wherein the fraction activates mast cells and basophils upon binding to a human own IgE antibody and has atopic dermatitis inducing activity of claim 9 for the same reasons as set forth in the Office Action mailed on 09/05/2008.

Applicant's argument filed on 12/08/2008 has been fully considered, but is not found persuasive.

Applicant argues:

"Again, Applicants note that the claims are product by process claims and do not require the structure of the claimed compound. Applicants further note that under the guidelines for examination of patent applications under the 35 U.S.C. § 112, paragraph one, "written description" requirement, the written description requirement for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics such as physical properties. It is noted that the claimed product-by-process indicates that the claimed fraction activates mast cells and basophils upon binding to a human own IgE antibody and having an atopic dermatitis inducing activity. Further, the claimed product-by-process discloses a method of obtaining the claimed composition. Thus, Applicants note that the specification and the claim indicate that Applicants had possession of the claimed genus, i.e., a fraction with the noted properties that was obtained by the method recited in the claims. "

It is the Examiner's position that "Possession may not be shown by merely describing how to obtain possession of member of the claimed genus or how to identify their common structural features" Ex parte *Kubin* (83 U.S.P.Q.2d 1410 (BPAI 2007)), at page 16. In the instant case, Applicants have not adequately described the composition comprising a sweat fraction that can be used. "Without a correlation between structure and function, the claim does little more than define the claimed invention by function" *supra*, at page 17. Definition by function does not suffice to define the genus of compositions encompassed because it is only an indication of what the composition does rather than what it is. Applicant's argument that structure is unnecessary because the claims are directed to a product by process is unpersuasive. The function alone is not sufficient to identify the instant compound, irrespective of the method of production. Therefore, the rejection stands.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 9 stands rejected under 35 U.S.C. 102(b) as being anticipated by Hide et al. (PTO-892 mailed 03/17/2008; Reference U) for the same reasons as set forth in the Office Action mailed on 09/05/2008.

Hide et al. teaches a purified composition which is obtained from human sweat that activates mast cells and basophils upon binding to human IgE antibody and has atopic dermatitis inducing activity (In particular, abstract, "Materials and Methods" sections, Figure 4, paragraph spanning left and right columns of page 339, whole document).

The recitation of "obtained from human sweat through the following steps comprising: filtering human sweat, removing insoluble matters and collecting the filtrate; mixing the filtrate with a ConA-affinity carrier and collecting the supernatant; and separating a fraction having a histamine-releasing activity from the supernatant by anion exchange column chromatography and reverse phase column chromatography" of claim 9 is included in this rejection because the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Further, once a product is fully disclosed in the art,

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future claims to that same product are precluded, even if that product is claimed as made by a new process.

The reference teachings anticipate the claimed invention.

Applicant's argument filed on 12/08/2008 has been fully considered, but is not found persuasive.

Applicant argues:

Applicants note that Hide et al. describes on page 339, right column, lines 13-19 that "a dot blot study of these fractions did not show any apparent binding of serum IgE in sera of these patients." Since the composition of the claimed invention is able to bind IgE, this composition is clearly different from the composition of Hide et al.

It is the Examiner's position that although the specific proteins mentioned on page 339, lines 13-19 do not bind IgE, the reference teaches in that same paragraph that there are two proteins which have been shown to bind IgE. Since the claims are directed to "fractions" and not specific proteins, the claims read on reference sweat fractions comprising a protein which binds IgE and another protein that activates mast cells and basophils upon binding to IgE and has atopic dermatitis inducing activity, as was shown to be present in the reference sweat fractions. Therefore, the rejection stands.

16. No claim is allowed.

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17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 27, 2009

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Nora M. Rooney

Patent Examiner

Technology Center 1600

/Maher M. Haddad/

Primary Examiner,

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